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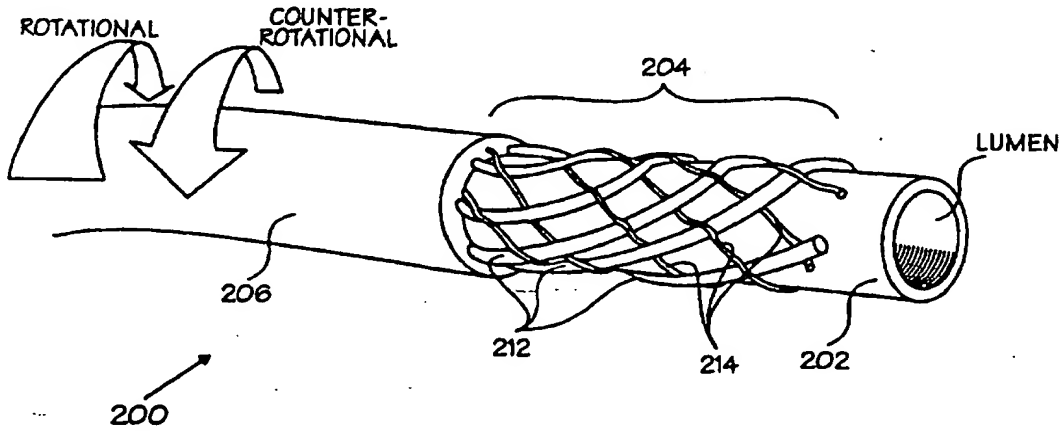

(57) Abstract

A flexible catheter comprising a reinforcement sheath made of helically disposed reinforcement elements. Different elements made of different material and having different thickness are used in different winding directions. By braiding thicker elements in a rotational direction, and by braiding substantially thinner elements in a counter-rotational direction, the kink-resistance, torsional stiffness and axial stiffness of the resulting catheter will be increased without increasing the catheter wall thickness. Thus, the same mechanical characteristics of catheters having thick catheter walls can be achieved in thin-walled catheters, greatly increasing the possible lumen diameter of the catheters. An even thinner catheter wall can be formed when the reinforcement elements are partially embedded into the wall of the inner tubular member.

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THIN-WALLED AND BRAID-REINFORCED CATHETER

FIELD OF THE INVENTION

The present invention generally relates to intravascular catheters, such as guiding catheters or diagnostic catheters used during percutaneous transluminal coronary angioplasty or microinvasive neuroradiology procedures, and any other catheters that can be introduced into a vasculature.

BACKGROUND OF THE INVENTION

With the advent of technology and surgical techniques, complicated surgical procedures such as transluminal coronary angioplasty and microinvasive neuroradiology have almost become routine for cardiologists and neuro-surgeons. In order to perform these procedures, as well as others such as laser angioplasty, angioscopy or intra-coronary atherectomy, it is necessary to introduce a catheter into an artery of the patient, and subsequently advance the catheter along the course of the artery or the other blood vessels to engage the target tissues. Surgical or diagnostic devices are often introduced within the catheter.

Conventional catheters, however, have a small lumen diameter, thus limiting the size and complexity of the surgical or diagnostic devices that can be introduced. Those catheter bodies are typically made of an inner plastic tube surrounded by and reinforced with a braided stainless steel mesh, and covered with an outer plastic sleeve. As shown in Figure 1, the braided steel mesh comprises helically disposed braid elements in both rotational and counter-rotational winding directions. Examples of such designs are disclosed in U.S. Patents 3,485,234 and 3,585,707. Those catheters are often manufactured by extruding a plastic tubing, and then braiding metal fibers or strands over the plastic tubing to form a braided tube. The plastic tubing must be sufficiently thick to act as a base around which the braid is woven. A second extruded layer of plastic is then applied over the braided tube. Those catheters, however, while providing desirable mechanical characteristics, usually lack desirable wall thickness and lumen diameter.

In order to develop catheters having a larger lumen diameter, catheter walls must be made as thin as possible. However, thin, under reinforced plastic tubing lacks desirable mechanical characteristics such as kink resistance, torsional stiffness and axial stiffness. An improved torsional stiffness permits torque to be better transmitted from a proximal end of the catheter to a distal tip to facilitate advancement of the catheter through the branching blood vessels of the patient. A high kink resistance is also desirable because, once a catheter kinks, it will lose its functionality. In additional, a high axial stiffness is desirable because an axial force is sometimes necessary to push the catheter through long and winding blood vessels to engage the target tissue.

Attempts have been made to optimize these mechanical characteristics. For example, in U.S. Patent 5,057,092 (Webster), a catheter comprising a flexible inner wall surrounded by a braided reinforcing mesh and a flexible plastic outer wall is disclosed. In Webster, the braided reinforcing mesh is interwoven with longitudinal wrap members having a low modulus of elasticity to increase axial stiffness. Such a braided reinforcing mesh can increase torque and or axial stiffness of the catheter. However, a major drawback of such a design is that as more reinforcing elements are involved, catheter wall thickness is necessarily increased, thus reducing the lumen diameter. Furthermore, that mesh design does not enhance the torque performance or pushability of the catheter, since identical braid members are used in both winding directions.

Other examples include U.S. Patents 5,176,660 and 5,019,057, both authored by the applicant herein. In those patents, the applicant discloses a flexible catheter comprising a resilient, tubular layer in telescopic relation with a tubular sheath made of helically disposed strands. In that design, at least one of the helically disposed strands that are comprised of the tubular sheath is flat and has a width that substantially exceeds its height. Furthermore, to increase axial stiffness, the catheter also requires at least one axial reinforcing element. However, although such a braid reinforcement element can enhance torque response and axial stiffness of the catheter, that design does not reduce the wall thickness. Furthermore, it is important to note that the braided structure disclosed in these two patents comprises a plurality of flat and round elements that are wound in both

rotational and counter-rotational directions. Because of this disposition of braid elements, such a design does not increase the torque response and pushability of the catheter.

Attempts have also been made to reduce wall thickness of prior art devices by reducing the thickness of the reinforcing elements and increasing their tensile strength. However, decreasing the diameter of the reinforcing elements will also decrease the kink resistance of the catheter.

The relationship between the kink-resistance of a catheter and the diameter of the reinforcing elements can be described in the formula below:

For a round reinforcing element:

$$I_{round} = D^4 \times \pi / 64$$

where D is the diameter of a round reinforcing element, and I_{round} is the kink resistance of the braided reinforcing sheath. And, for a rectangular reinforcing element:

$$I_{rectangular} = A^3 \times B / 12$$

where A and B are the dimensions of a rectangular reinforcing element.

Thus, decreasing the diameter or cross-sectional area of the reinforcing elements will reduce the kink resistance of the catheter. The increased tensile strength cannot compensate for the reduced kink-resistance of these constructions, and therefore, when sharply bent, a catheter constructed with thin reinforcing elements only will become excentric (collapse), reducing its torque performance. The catheter may also kink and lose its functionality.

Other prior art devices attempted to reinforce the catheter with coil-like structures. However, coils tend to have good torque transmission only in one direction (in the winding direction). A rotational force applied opposite to the coil's winding direction tends to open the coil structure, and therefore, the rotational force is not transmitted. Coil structures do not provide sufficient torque transmission capability because the reinforcing members are not interlaced with other reinforcing members. As a result, if a torque is applied to a proximal end of the coil structure, the coil will increase or decrease its nominal diameter depending on the direction of the torque, rather than transmitting the torque to a distal end.

None of the prior art devices above has a high torsional stiffness, a high axial stiffness and a high kink resistance without sacrificing wall thickness. What is needed is a flexible catheter having the largest possible lumen diameter without losing torsional stiffness, axial stiffness, and kink resistance.

SUMMARY OF THE INVENTION

An object of the present invention is to provide a reinforcement structure for and a method of constructing a catheter with minimum wall thickness and maximum axial stiffness, torsional stiffness, and kink-resistance.

In the preferred embodiment of the invention, a flexible catheter comprises at least one tubular member which is surrounded by a tubular sheath made of helically disposed crossing strands. The novelty in this invention is the use of braid elements having different thicknesses and/or different elasticities in different winding directions. By braiding thicker, higher bending modulus elements in a rotational direction, and by braiding substantially thinner, higher elastic modulus elements in a counter-rotational direction, the torsional and axial stiffness of the resulting catheter will be increased without increasing the catheter wall thickness. Thus, the same mechanical characteristics of catheters having thick catheter wall can be achieved in thinner walled catheters, greatly increasing the possible lumen diameter of the catheters. Kink resistance is also increased because, by interweaving smaller diameter elements with larger diameter elements, the larger elements are able to maintain a near-perfect helical shape, thus increasing the radial strength and kink resistance of the catheter. The high elastic modulus of the thinner elements keep the thicker elements in place to ensure uniform torque performance in both rotational and counter-rotational directions.

To further reduce the wall thickness, a catheter can be made such that some of the braid elements are partially embedded into the wall of the inner tubular member. Such a catheter can be manufactured by first applying a thin inner tubular member over a stretchable mandrel. Braid elements are then wound tightly around the thin inner tubular member to form a braided-tube/mandrel assembly. After an outer tubular member is applied over the braided-tube/mandrel assembly, a tension is applied to the mandrel such

that it is straightened. The braided tube and the outer tubular member are then fused together. The assembly is then cooled and the mandrel is stretched to a point such that its diameter is reduced. The constricted mandrel can then be readily removed and discarded. By using a stretchable mandrel, a thin walled inner tubular member can be used in spite of the inward pressure resulting from the tight braiding. The step of stretching the mandrel, and thus reducing its diameter, allows the mandrel to be easily removed. This process also allows non-extrudable materials such as PTFE to be used for forming the inner tubular member.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 illustrates a prior art catheter reinforced with symmetrically disposed braid elements in both winding direction.

Figure 2 illustrates a partial cut-away view of the preferred embodiment of the present invention.

Figure 3 illustrates a cross-sectional view of the preferred embodiment of the present invention.

Figure 4 illustrates the steps necessary for manufacturing the present invention.

Figure 5 illustrates an alternate embodiment of the present invention where the braid elements are not partially embedded into the wall of the inner tubular member.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 2 shows a telescopic view of the reinforced catheter in accordance with the present invention. A braided structure 204 is formed over an inner tubular member 202, and is encapsulated by an outer tubular member 206 to form a composite catheter body 200. All large diameter elements 212 of the braided reinforcement structure 204 are wound helically in a same rotational direction. All small diameter elements 214 of the braided structure 204 are interwoven with the large diameter elements 212 and are wound in a counter-rotational direction. The small diameter elements 214 and the large diameter elements 212 can be braided using methods known in the prior art. The large diameter elements 212 are preferably made of metallic materials such as stainless steel, nitanol

alloy, copper or any other material suitable for braiding. The material would preferably have a high bending stiffness. Other materials such as carbon or fused silica fibers can also be used.

It is not required that all the large diameter elements 212 are uniformly made of one material. Depending on the intended application of the catheter and the desired mechanical characteristics, different combinations of large diameter elements 212 made of different materials may be used. Furthermore, it is not required that all large diameter elements have an identical diameter or cross-sectional area. Again, depending on the application of the catheter and the materials used, the large diameter elements 212 may comprise filaments of different diameters, as long as they are substantially thicker than the small diameter elements 214.

All small diameter elements 214 are wound helically in the counter-rotational direction and are interlaced with the large diameter elements to form the braided structure 204. The small diameter elements 214 are made of preferably high tensile strength materials, such as high tensile strength stainless steel, kevlar or any other metallic or non-metal suitable for braiding. It is not necessary that all the small diameter elements are made of a single material. Depending on the application of the catheter and the desired mechanical characteristics, the small diameter elements 214 may comprise a multitude of materials. Furthermore, the small diameter elements 214 may also comprise filaments of different diameters, as long as they are substantially thinner than the large diameter elements 212.

In this construction, the larger diameter elements with a bending stiffness are responsible for the maintaining the high kink resistance of the catheter. However, without the high tensile strength small diameter elements locking the large elements in place, the large diameter elements will have poor torque performance when a counter-rotational force is applied. As discussed above, coils tend to have good torque transmission only in one direction (in the winding direction). In order to provide good torque performance and kink resistance, small diameter elements with high tensile strength are wound in the counter-rotational direction to keep the large diameter elements in place, assuring uniform torque performance in both rotational and counter-rotational directions.

Figure 3 is a cross-sectional view of the preferred embodiment of the present invention. To further reduce catheter wall thickness, the braid elements 312 and 314 could be embedded at least partially into the wall of the inner tubular member 302.

It is understood that the present invention is not intended to be limited by a cross-sectional shape of the braid elements. The figures, showing braid elements having a round cross-sectional shape, are intended for illustration purposes only. It is understood that braid elements having different cross-sectional shapes can also be used, and that they are also intended to be covered by this patent. Furthermore, it is also understood that round braid elements should have an oblong cross-sectional shape because the cross-section is made at an angle to the braid element. However, for the sake of simplicity, the cross-section of the braid elements are shown to be round. In addition, it is understood that the diagrams illustrate 8 large diameter elements interwoven with 8 small diameter elements for illustration purposes only. The number of large diameter elements and the number of small diameter elements do not have to be the same, and the number is not limited to 8. It should also be understood that large diameter elements have a larger bending stiffness than the small diameter elements.

Figures 4a-c illustrate the steps which are necessary for the manufacture of the preferred embodiment of the present invention. According to Figure 4a, an inner tubular member 402 made of PTFE is placed over an annealed stretchable copper mandrel 401 (or other suitable mandrel such as an annealed stainless steel mandrel) in such a way that both ends of the mandrel 401 extend out from the inner tubular member 402. Preferably, the inner tubular member 402 has been chemically etched for enhanced braiding capabilities. The mandrel 401 has a diameter approximately the same as an inside diameter of the inner tubular member 402. This assembly is fed into a braiding machine where braid elements 412 and 414 are braided tightly around the inner tubular member 402. Preferably, the braiding can be sufficiently tight that some of the braid elements 412 and 414 are partially embedded into the inner tubular member 402 to form a braided assembly 420, as shown in Figure 4b. After the braiding operation, an outer tubular member 406 is placed over the braided assembly 420 such that the outer tubular mandrel 406 covers at least partially the inner tubular member 402, as shown in Figure 4c. The

outer tubular member 406 can be constructed from thermoplastic elastomer such as nylons, urethane, or other suitable materials. After the outer tubular member 406 is placed, a heat shrinkable tubing (such as FEP) is placed over the outer tubular member 406.

Because the mandrel 401 is made of a stretchable material, the mandrel 401 is malleable and by this time would be bent in several directions from handling during the braiding and tube assembly processes. If fusing occurs when the mandrel is bent, the resulting catheter will also be crooked. Therefore, it is necessary to straighten the mandrel 401 before the final fusing process takes place. A straightening force can be applied in a fusing machine to straighten the mandrel 401. However, the straightening force should be small enough to prevent stretching the mandrel 401 to the point that would reduce its diameter more than 0.001". A heat process can be used to shrink the heat shrinkable tubing, melting and fusing the inner and outer tubular members together to a form a cohesive composite structure. After the fusing process and after the catheter is cooled to an ambient temperature, a second stretching force is applied to the mandrel 401 to reduce its diameter so that it can be removed from the assembly. The heat shrunk tube can be removed by simply cutting it away. This process allows very thin materials such as PTFE to be made into the inner tubular member 402. This is because the mandrel 401 provides sufficient structure to support the braiding operation. Ordinarily, the pressure between the catheter structure and the mandrel would prevent ready removal of the mandrel. However, in here, because a stretchable mandrel is used the catheter can be formed with the thin walled tubular members 402.

Construction of the braided reinforcement sheath, however, is not limited to this manufacturing method. A continuous extrusion process can also be used. Using this method, a plastic inner tubular member is continuously extruded over a stretchable mandrel wire. Then, reinforcing elements are braided over the plastic inner tubular member to form a braided assembly. The braided assembly is fed through a second extrusion machine where an outer tubular member is extruded over and fused with the braided assembly to form a composite structure. The stretchable mandrel can be stretched to a reduce its diameter such that the mandrel can be removed from the catheter lumen.

Figure 5 shows the cross-sectional view of an alternate embodiment of the present invention where reinforcing elements 512 and 514 are embedded into an outer tubular member 506, but are not embedded into an inner tubular member 502. The catheter in this case can be built in the following steps. A braided sheath is formed in a separate mandrel and is then transferred over an inner tubular member-metal mandrel assembly with very low tension on the individual braiding elements to prevent the braid to lock on to the stainless steel mandrel. An outer tubular member 506 at this point can be placed over the braid-inner tubular member-mandrel assembly. The outer tubular member 506 will then be fused together with the inner tubular member-braided sheath-mandrel assembly with the help of a heated die or with the aid of a suitable heat shrinkable tubing. The heat shrinkable tubing can be removed after the fusing process (can be cut away too), and the stainless steel mandrel can be removed by pulling it out from the composite tubular structure.

Many long-felt needs in the field of catheters have been fulfilled by the present invention. A catheter made according to the present invention by interlacing thick braiding elements in one direction with thin braiding elements in an opposite direction allows thinner walled catheters to be made. Desirable mechanical characteristics such as torsional stiffness, axial stiffness and kink resistance can now be achieved without sacrificing wall thickness. Furthermore, by braiding the braid elements over a stretchable mandrel, wall thickness is further decreased because the braid elements can be partially embedded into the inner tubular wall of the catheter. Thin, non-extrudable materials such as PTFE may now be used to form the inner tubular member.

The present invention has been described in terms of specific embodiments incorporating details to facilitate the understanding of the principles of construction and operation of the invention. Such reference herein to specific embodiments and details thereof is not intended to limit the scope of the claims appended hereto. It will be apparent to those skilled in the art that modifications may be made in the embodiment chosen for illustration without departing from the spirit and scope of the invention.

CLAIMS

What is claimed is:

1. A catheter for insertion into a human vasculature, comprising:
   a. a first tubular member; and
   b. a braided reinforcing sheath in concentric relation to the first tubular member, the reinforcing sheath comprising a first strand interlaced with a second strand, wherein the first strand is helically disposed in an opposite winding direction to the second strand, wherein the first strand is substantially thicker than the second strand.

2. The catheter according to claim 1, further comprising a second tubular member in concentric relation to and surrounding the braided reinforcing sheath.

3. The catheter according to claim 1, wherein the reinforcing sheath further comprises a plurality of first strands interlaced with a plurality of second strands, each of the first strands being helically disposed in a rotational winding direction, each of the second strands being helically disposed in a counter-rotational winding direction.

4. The catheter according to claim 3, wherein each of the plurality of first strands is made of a first material and each of the plurality of second strands is made of a second material.

5. The catheter according to claim 4, wherein the first material has a higher bending stiffness than the second material.

6. The catheter according to claim 4, wherein the first material is metallic and the second material is non-metallic.

7. The catheter according to claim 1, wherein the first strand is made of a first material and the second strand is made of a second material, wherein the first material and the second material have high elastic modula, further wherein the first material having a higher bending stiffness than that of the second material.

8. The catheter according to claim 1, wherein the braided reinforcing sheath is partially embedded into a wall of the inner tubular member.

9. A flexible, thin-walled and kink-resistant catheter for insertion into a human vasculature, comprising:

a. an inner tubular member made of PTFE;

b. a first plurality of strands helically interlacing in opposite winding directions to a second plurality of strands to form a braided sheath, the first strands and the second strands both being wound onto the inner tubular member, wherein each of the first strands is substantially thicker than each of the second strands; and

c. an outer tubular member formed by fusing a second thermoplastic material over the braided reinforcing sheath.

10. The catheter according to claim 9, wherein the PTFE is formed over a stretchable mandrel.

11. The catheter according to claim 9, wherein the inner tubular member, the braided reinforcing sheath, and the outer tubular member are fused together to form a composite structure.

12. The catheter according to claim 9, wherein the first strands are made of a first material and the second strands are made of a second material, wherein the first material has a higher bending stiffness than the second material.

13. The catheter according to claim 12, wherein the first material and the second material have high elastic modula.

14. A flexible, thin-walled and kink-resistant catheter for insertion into a human vasculature, comprising:

a. an inner tubular member made of PTFE;

b. a braided reinforcing sheath in concentric relation with the inner tubular member, the reinforcing sheath comprising a plurality of first strands helically interlaced with a plurality of second strands, each of the first strands being helically disposed in a first winding direction, each of the second strands being helically disposed in a second winding direction, each of the first strands being substantially thicker than each of the second strands, each of the first strands being made of a first material and each of the second strands being made of a second material, wherein the first material and the second material have a high elastic modulus, further wherein the first material has a higher bending stiffness than the second material; and

c. an outer tubular member.

15. A method of manufacturing a catheter for insertion into a human vasculature, comprising the steps of:

a. placing a first tubular member over a stretchable mandrel, the stretchable mandrel having two ends, such that both ends of the stretchable mandrel extend out from the first tubular member, wherein the first tubular member is made of PTFE;

b. braiding reinforcement filaments over the first tubular member to form a reinforcing mesh, the filaments being partially embedded into the first tubular member;

c. placing a second tubular member over the reinforcement mesh;

d. fusing the second tubular member to the reinforcement filaments and the first tubular member; and

e. removing the mandrel by stretching the stretchable mandrel to reduce a diameter of the stretchable mandrel.

16. The method according to claim 15, further comprising the step of applying a tension to both ends of the stretchable mandrel to straighten the stretchable mandrel and the first tubular member prior to the step of fusing.

17. The method according to claim 15, wherein the reinforcement filaments comprise a plurality of first strands helically interlaced with a plurality of second strands, each one of the first strands being helically disposed in a first winding direction, each one of the second strands being helically disposed in a second winding direction, further wherein each of the first strands is substantially thicker than each of the second strands.

18. The method according to claim 17, wherein each of the first strands is made of a first material, wherein each of the second strands is made of a second material.

19. The method according to claim 15, further comprising the step of cooling a fused assembly comprising the mandrel, the inner tubular member, the braided sheath, and the outer tubular member prior to the step of removing.

20. A method of forming a catheter, comprising:

a. applying the tubular layer of PTFE to a stretchable mandrel, the stretchable mandrel having two ends;

b. braiding reinforcement filaments over the tubular layer of PTFE to form a reinforcing mesh, the filaments being partially embedded into the tubular layer of PTFE;

c. applying a first tension to the stretchable mandrel by pulling the two ends for straightening the stretchable mandrel;

d. applying a tubular layer of thermoplastic over the reinforcing mesh;

e. fusing the tubular layer of thermoplastic to the reinforcing mesh and the tubular of PTFE by heat to form a composite structure;

f. cooling the composite structure to an ambient temperature;

g. applying a second tension to the stretchable mandrel to reduce a diameter of the stretchable mandrel such that the stretchable mandrel can be readily removed from the composite structure; and

h. removing the stretchable mandrel from the composite structure.

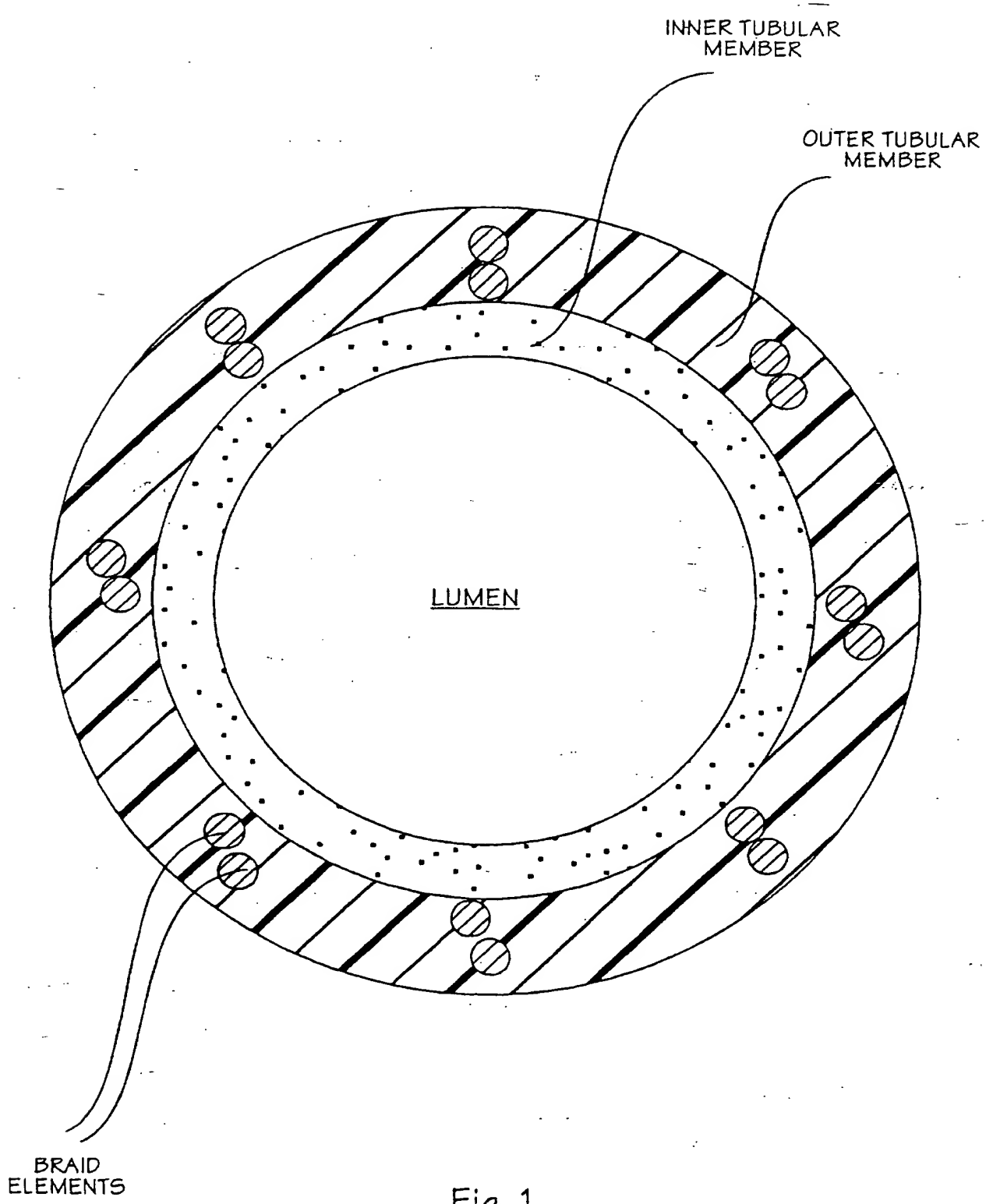

Fig. 1
(Prior Art)

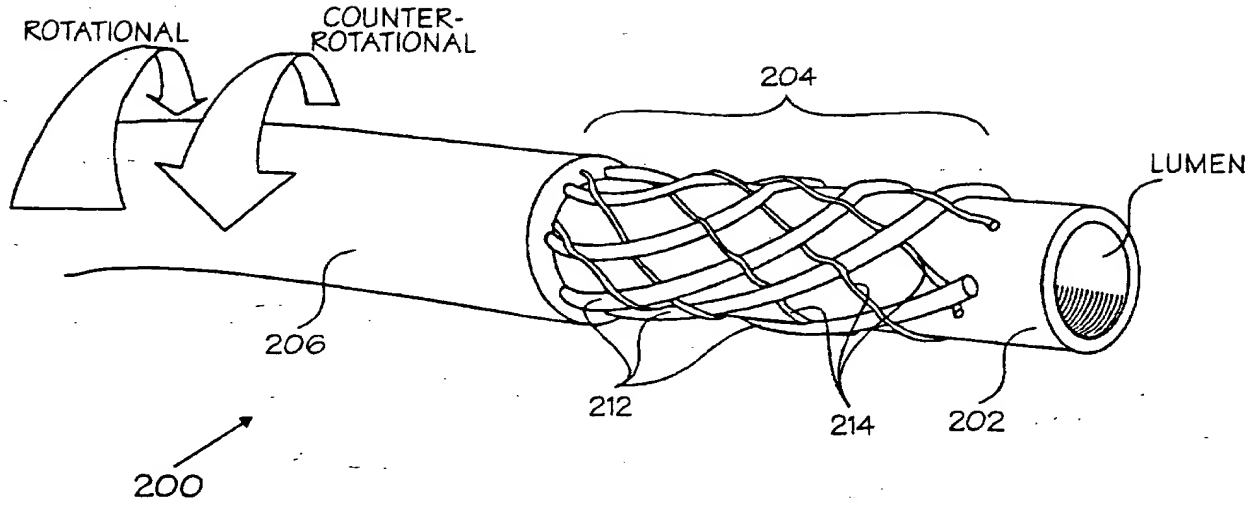

Fig. 2

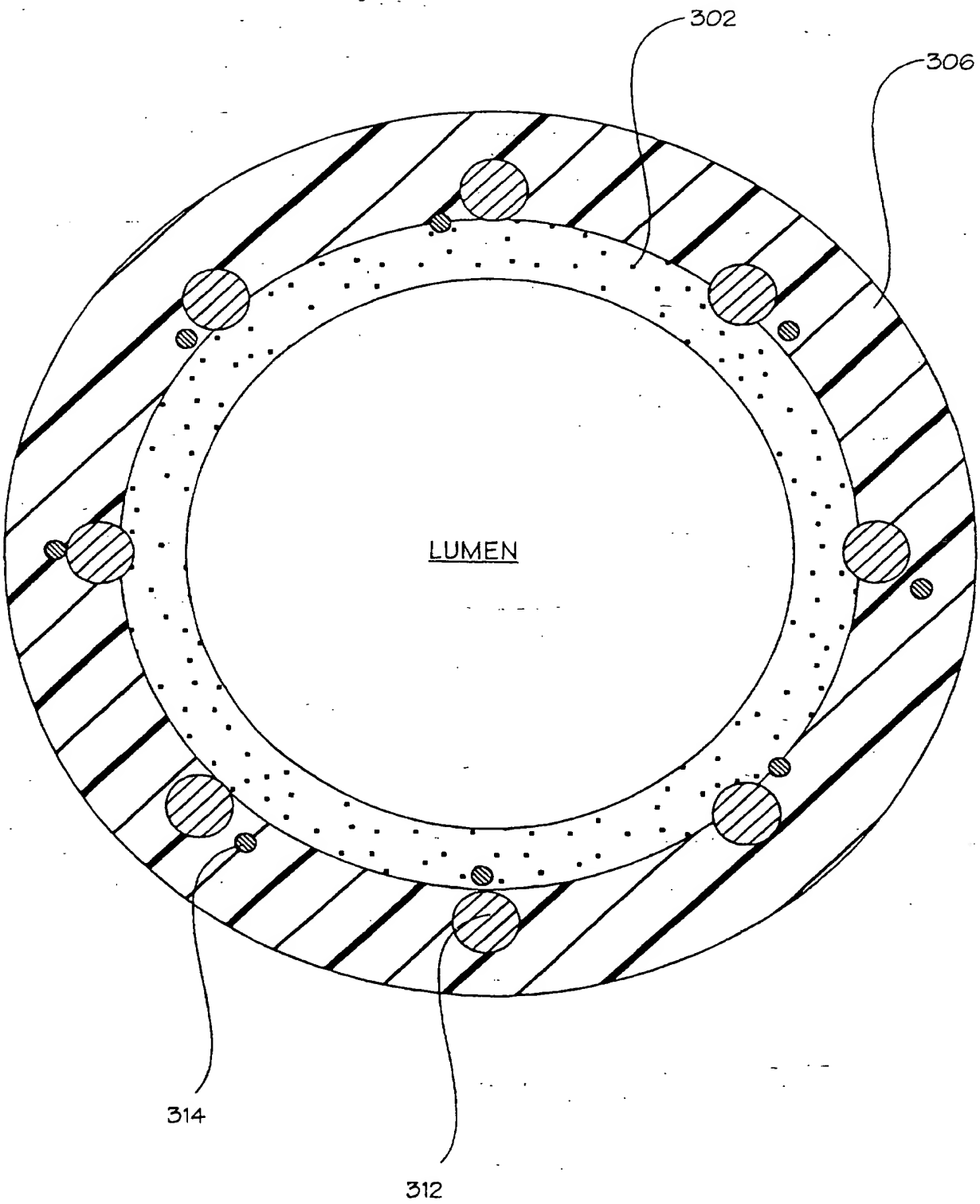

Fig. 3

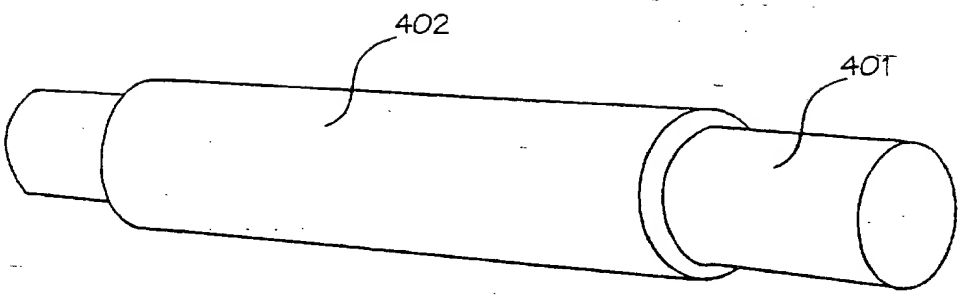

Fig. 4A

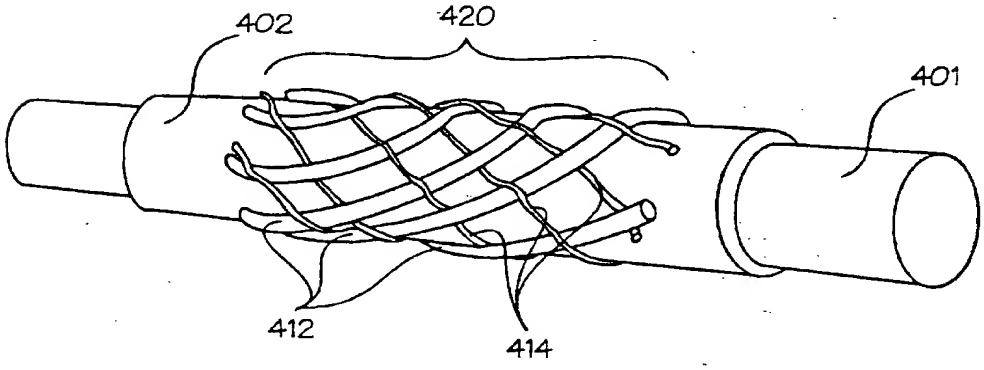

Fig. 4B

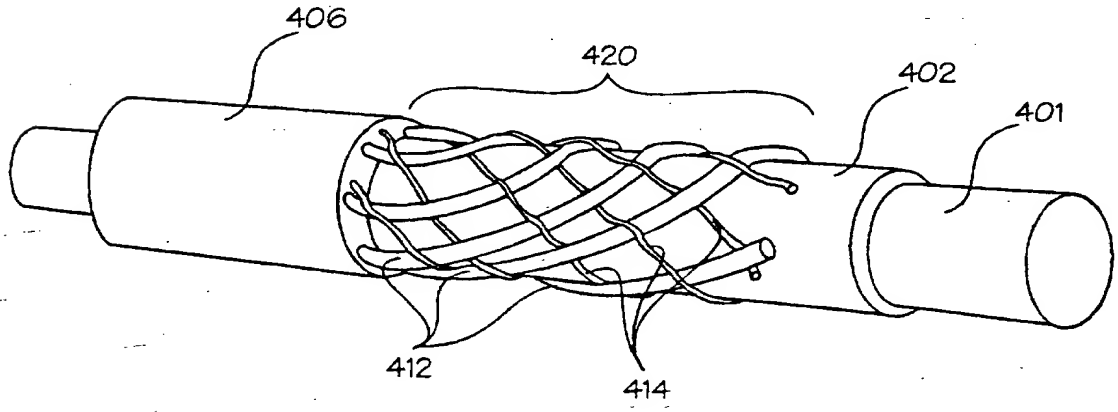

Fig. 4C

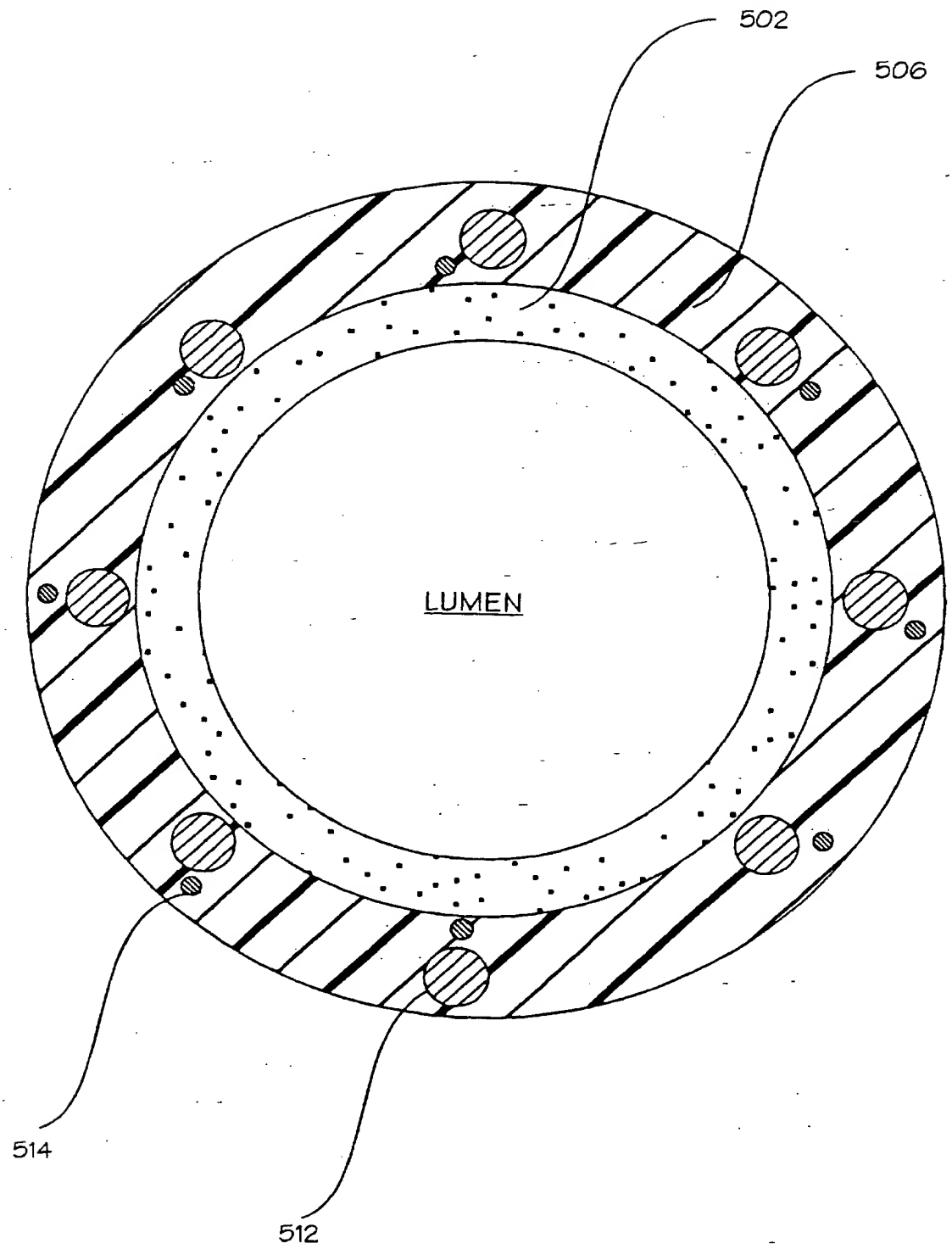

Fig. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/05625

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	EP 0 732 117 A (ASAHI INTECC CO LTD) 18 September 1996 see column 3, line 25 - column 4, line 18; figures	1-20
X	US 5 454 795 A (SAMSON) 3 October 1995 see column 7, line 43 - column 8, line 51; figure 6	1-14
X Y	US 5 019 057 A (TRUCKAI) 28 May 1991 cited in the application see column 4, line 2 - line 53; figures	1-8 9-20
X	US 5 057 092 A (WEBSTER JR) 15 October 1991 cited in the application see page 3, line 19 - line 68; figure 5	1-8

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"P" document published prior to the international filing date but later than the priority date claimed

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Date of the actual completion of the international search	Date of mailing of the international search report
4 August 1997	13.08.97

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Clarkson, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 97/05625

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	WO 91 13648 A (W.L.GORE) 19 September 1991 see the whole document -----	9-20

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internauonal Application No
PCT/US 97/05625

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